AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Original) A pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form.

2. (Original) The pharmaceutical composition according to Claim 1, wherein the complex is saturated with cladribine.

3. (Previously Presented) The composition according to Claim 1, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

4. (Previously Presented) The composition according to Claim 1, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

5. (Previously Presented) The composition according to Claim 1, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

6. (Currently Amended) The composition according to Claim 1, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

7. (Original) The composition according to Claim 6, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

8. (Original) The composition according to Claim 7, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

9. (Original) The composition according to Claim 7, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

10. (Original) The composition according to Claim 6, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

11. (Previously Presented) The composition according to Claim 1, wherein the approximate molar ratio of cladribine to amorphous cyclodextrin corresponds to a point located on a phase solubility diagram for saturated complexes of cladribine in varying concentrations of the cyclodextrin.

12. (Previously Presented) The composition according to Claim 1, wherein from about 30 to about 40 percent by weight of the cladribine is in the

inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

13. (Original) A method for enhancing the oral bioavailability of cladribine comprising orally administering to a subject in need thereof a pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form.

14. (Original) The method according to Claim 13, wherein the complex is saturated with cladribine.

15. (Previously Presented) The method according to Claim 13, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

16. (Previously Presented) The method according to Claim 13, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

17. (Previously Presented) The method according to Claim 13, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

18. (Previously Presented) The method according to Claim 13, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

19. (Original) The method according to Claim 18, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

20. (Original) The method according to Claim 19, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

21. (Original) The method according to Claim 19, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

22. (Original) The method according to Claim 18, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

23. (Previously Presented) The method according to Claim 13, wherein the approximate molar ratio of cladribine to amorphous cyclodextrin corresponds to a point located on a phase solubility diagram for saturated complexes of cladribine in varying concentrations of the cyclodextrin.

24. (Previously Presented) The method according to Claim 13, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion

complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

25. (Original) A method for the treatment of symptoms of a cladribine-responsive condition in a subject suffering from said symptoms comprising orally administering to said subject a pharmaceutical composition comprising a complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex, formulated into a solid oral dosage form.

26. (Original) The method according to Claim 25, wherein the complex is saturated with cladribine.

27. (Previously Presented) The method according to Claim 25, wherein the cladribine-responsive condition is selected from the group consisting of multiple sclerosis, rheumatoid arthritis and leukemia.

28. (Original) The method according to Claim 27, wherein the cladribine-responsive condition is multiple sclerosis.

29. (Previously Presented) The method according to Claim 25, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin,

hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

30. (Previously Presented) The method according to Claim 25, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

31. (Previously Presented) The method according to Claim 25, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

32. (Original) The method according to Claim 31, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

33. (Original) The method according to Claim 31, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

34. (Previously Presented) The method according to Claim 25, wherein the amorphous cyclodextrin is hydropropyl-γ-cyclodextrin.

35. (Previously Presented) The method according to Claim 25, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

36.-55. (Cancelled)

56. (Original) A complex cladribine-cyclodextrin complex which is an intimate amorphous admixture of (a) an amorphous inclusion complex of cladribine with an amorphous cyclodextrin and (b) amorphous free cladribine associated with amorphous cyclodextrin as a non-inclusion complex.

57. (Original) The complex according to Claim 56, saturated with cladribine.

58. (Previously Presented) The complex according to Claim 56, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin, hydroxypropyl-γ-cyclodextrin, randomly methylated β-cyclodextrin, carboxymethyl-β-cyclodextrin or sulfobutyl-β-cyclodextrin.

59. (Previously Presented) The complex according to Claim 56, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

60. (Previously Presented) The complex according to Claim 56, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

61. (Previously Presented) The complex according to Claim 56, wherein the weight ratio of cladribine to amorphous cyclodextrin is from about 1:10 to about 1:16.

62. (Original) The complex according to Claim 61, wherein the amorphous cyclodextrin is hydroxypropyl-β-cyclodextrin.

63. (Original) The complex according to Claim 62, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:14.

64. (Original) The complex according to Claim 62, wherein the weight ratio of cladribine to hydroxypropyl-β-cyclodextrin is about 1:11.

65. (Original) The complex according to Claim 61, wherein the amorphous cyclodextrin is hydroxypropyl-γ-cyclodextrin.

66. (Previously Presented) The complex according to Claim 56, wherein from about 30 to about 40 percent by weight of the cladribine is in the inclusion complex (a) and from about 70 to about 60 percent by weight of the cladribine is in the non-inclusion complex (b).

67. (Currently Amended) A process for the preparation of a complex cladribine-cyclodextrin complex as claimed in Claim 56, which comprises the steps of:

(i) combining cladribine and an amorphous cyclodextrin in water at a temperature of from about 40 to about 80°C and maintaining said temperature for a period of from about 6 to about 24 hours;

(ii) cooling the resultant aqueous solution to room temperature; and

(iii) lyophilizing the cooled solution to afford an amorphous product.

68. (Original) A process according to Claim 67, further comprising a filtration step following step (ii).

69. (Previously Presented) A process according to Claim 67, wherein step (i) is performed at a temperature of from about 45 to about 60°C.

70. (Previously Presented) A process according to Claim 67, wherein step (i) is performed at a temperature of from about 45 to about 50°C.

71. (Previously Presented) A process according to Claim 69, wherein step (i) is performed with stirring.

72. (Original) A process according to Claim 71, wherein step (i) is performed for a period of from about 6 to about 9 hours.

73. (Previously Presented) A process according to Claim 67, wherein step (ii) is performed for a period of from about 6 to about 9 hours.

74. (Previously Presented) A process according to Claim 67, wherein step (iii) comprises an initial freezing stage in which the solution is cooled to from

about -40 to about -80° C, and held at said temperature for a period of from about 2 to about 4 hours.

75. (Original) A process according to Claim 74, wherein, in the initial freezing stage of step (iii), the solution is cooled to about -45°C.

76. (Previously Presented) A process according to Claim 67, wherein 12.00 parts by weight of cladribine and 172.50 parts by weight of hydroxypropyl-β-cyclodextrin are introduced in step (i).

77. (Previously Presented) A process according to Claim 67, wherein 16.35 parts by weight of cladribine and 172.50 parts by weight of hydroxypropyl-β-cyclodextrin are introduced in step (i).

78. (Previously Presented) A process according to Claim 76, wherein 825 parts by volume of water are introduced in step (i).

79. (Previously Presented) A process according to Claim 67, wherein the lyophilization step (iii) comprises:

(a) an initial freezing stage in which the complexation solution is brought to from about -40°C to about -80°C for approximately 2 to 4 hours;

(b) a primary drying stage at about -25°C for approximately 80 to 90 hours; and

(c) a secondary drying stage at about 30°C for approximately 15 to 20 hours.

80. (Original) A process according to Claim 79, wherein stage (a) of the lyophilization is conducted at about -45°C for approximately 3 to 4 hours.

81. (Previously Presented) A process according to Claim 79, wherein stage (b) of the lyophilization is conducted under a pressure of about 100 mTorr.

82. (Original) A pharmaceutical composition obtainable by a process comprising the steps of:

(i) combining cladribine and an amorphous cyclodextrin in water at a temperature of from about 40 to about 80°C and maintaining said temperature for a period of from about 6 to about 24 hours;

(ii) cooling the resultant aqueous solution to room temperature;

(iii) lyophilizing the cooled solution to afford an amorphous product; and

(iv) formulating the amorphous product into a solid oral dosage form.

83. (Original) A pharmaceutical composition according to Claim 82, wherein the process further comprises a filtration step following step (i) or (ii).

84. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (i) of the process is performed at a temperature of from about 45 to about 60°C.

85. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (i) of the process is performed at a temperature of from about 45 to about 50°C.

86. (Previously Presented) A pharmaceutical composition according to Claim 84, wherein step (i) of the process is performed with stirring.

87. (Original) A pharmaceutical composition according to Claim 86, wherein step (i) of the process is performed for a period of from about 6 to about 9 hours.

88. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (ii) of the process is performed for a period of from about 6 to about 9 hours.

89. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein step (iii) comprises an initial freezing stage in which the solution is cooled to from about -40 to about -80°C, and held at said temperature for a period of from about 2 to about 4 hours.

90. (Original) A pharmaceutical composition according to Claim 89, wherein, in the initial freezing stage of step (iii), the solution is cooled to about -45°C.

91. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein 12.00 parts by weight of cladribine and 172.50 parts by weight of the hydroxypropyl-β-cyclodextrin are introduced in step (i) of the process.

92. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein 16.35 parts by weight of cladribine and 172.50 parts by weight of the hydroxypropyl-β-cyclodextrin are introduced in step (i) of the process.

93. (Previously Presented) A pharmaceutical composition according to Claim 91, wherein 825 parts by volume of water are introduced in step (i) of the process.

94. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein the lyophilization step (iii) of the process comprises:

(a) an initial freezing stage in which the complexation solution is brought to from about -40°C to about -80°C for approximately 2 to 4 hours;

(b) a primary drying stage at about -25°C for approximately 80 to 90 hours; and

(c) a secondary drying stage at about 30°C for approximately 15 to 20 hours.

95. (Original) A pharmaceutical composition according to Claim 94, wherein stage (a) of the lyophilization is conducted at about -45°C for approximately 3 to 4 hours.

96. (Previously Presented) A pharmaceutical composition according to Claim 94, wherein stage (b) of the lyophilization is conducted under a pressure of about 100 mTorr.

97. (Previously Presented) A pharmaceutical composition according to Claim 82, wherein the formulation step (iv) of the process comprises blending the complex with magnesium stearate and compressing into tablets.

98. (Original) A pharmaceutical composition according to Claim 97, wherein magnesium stearate is pre-mixed with sorbitol powder before blending with the complex.